K955864

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS **EXHIBIT C**

Regulatory Authority:	Safe Medical Devices Act of 1990, 21 CFR 807.92
Company:	J.B.S. Parc d'activities Savipol 10300 Ste. Savine, Troyes Tel: 011-33-2571-2500 Fax: 011-33-2571-2506
Medical Device Establishment Registration #:	9681258
FDA Owner/Operator #:	9021265
Contact:	Ms. Liza Burns, Regulatory Consultant
Trade Name:	J.B.S. POSTERIOR C1-C2 CLAMP SYSTEM®
Common Name:	Cervical Clamp System
Classification Name:	Appliance, Fixation, Spinal Interlaminal
Classification Code:	87KWP

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Device Description: The J.B.S. Posterior C1-C2 Clamp System is a single-use, temporary device used for fixation of the C1-C2 vertebrae. The System is to be removed after fusion occurs. It consists of a cervical hook, a superior hook, a linking screw and a locking screw. All these components are made of surgical implant titanium with the composition Ti-6AL-4V ELI according to ASTM-136-92 or ISO 5832-3-90.

Indications for use: Fixation of C1-C2 in case of fracture or multi-operated back.

Contraindications: The J.B.S. Posterior C1-C2 Clamp System is <u>not</u> to be used for patients with active localized or systemic infection, patients who are pregnant or patients who have a disease or other medical condition which inhibits the potential of bony fusion (i.e., osteoporosis, kidney dialysis, etc.).

Substantially Equivalent Devices:

1. The APOFIX fixation device by Sofamor Danek (K945022)
2. The HALIFAX clamp

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So. San Francisco, CA 94080

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